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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,206	07/18/2003	Thomas P. Osypka	(49363) 58951	2847
21874	7590	02/16/2006	EXAMINER	
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BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/623,206

**Applicant(s)**

OSYPKA, THOMAS P.

**Examiner**

Eric D. Bertram

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/08/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 12/8/2003 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

2. The disclosure is objected to because of the following informalities: on page 5, line 19 "delivery device if" should be -- delivery device of -- and on page 12, line 9 it is believed that "configured for articulated" should be -- configured for articulation --.

Please review the specification for additional errors.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 18-20 are objected to because of the following informalities: in each claim, the phrase "according top" should be -- according to --. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kristiansen (US 5,242,431). Kristiansen discloses a device 10 for

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delivering and anchoring cardiac leads to an implantation site (Col. 3, lines 25-28). As shown in figure 1, the device comprises an elongated carrier body 14 with proximal end 18 and distal end 28, the body defining an interior channel 18 for carrying an implantable cardiac lead 12 (Col. 3, lines 37-40). The device also includes a collar 50 that is mounted on the carrier body and is slidable along the carrier body in order to grip and secure the lead body (see claim 1). As shown in figure 1, the distal end is tapered at 34, which effectively forms a protective shroud since it completely surrounds the lead body.

6. Claims 1, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher et al. (US 4,972,847). Dutcher et al. disclose a device and method for delivering an implantable cardiac lead including an elongated carrier body 20 having a proximal end at 48 and a distal end at 47, where the carrier body has two elongated beams 37 and 38 which define an interior channel that holds the lead 21 (see figure 1 and Col. 3, lines 25-30). The beams 37 and 38 further secure the lead 21 in the channel by clamping down in a closed position. After positioning the carrier body at an implantation site, the carrier body is rotated in order to screw the lead head into the cardiac tissue and effectively deploy the lead at the implantation site (Col. 7, lines 6-12). The cardiac lead is then released from the carrier body by squeezing the beams 37 and 38 (Col. 6, lines 64-68).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 2, 3, 10, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Kristiansen ('431). Dutcher et al., as described above, disclose the applicant's basic invention with the exception of having a collar mounted for adjustable movement on the carrier body. Attention is directed to the secondary reference of Kristiansen, which discloses a method and device for securing a lead body that includes the use of a collar 50 that is mounted on the carrier body and is slidable along the carrier body in order to grip and secure the lead body (see claim 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the delivery system of Dutcher et al. by adding the collar of Kristiansen since this is an old and well-known method in the art for securing lead bodies.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Ricciardelli et al. (US 4,644,957). Dutcher et al., as described above, discloses the applicant's basic invention with the exception of a journaled handle

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assembly for effectuating axial rotation of the carrier body. Attention is directed to the secondary reference of Ricciardelli et al., that discloses a journaled handle assembly comprising handle 15, shaft 16, and carrier body 10, such that by gripping the handle, the carrier body could then be axially rotated around the shaft by turning the body (see figure 1 and Col. 6, lines 22-26). Therefore, it would have been obvious to one of ordinary skill in the art to modify the delivery system of Dutcher et al. by adding the journaled handle assembly of Ricciardelli et al. since this is an old and well known method in the art for rotating carrier bodies to assist in delivering leads to implantation sites.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Dutcher et al. (US 4,209,019). Dutcher et al. ('847), as described above, disclose the applicant's basic invention with the exception of having the distal end of the carrier body tapered to form a shroud. Attention is directed to the secondary reference of Dutcher et al. ('019), which shows in figure 1 the distal end of carrier body 10 having tapered part 16 which helps form a shroud around the helix 42. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the delivery system of Dutcher et al. ('847) by adding a tapered distal end in order to add a shroud that protects the helix prior to implantation.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Dutcher et al. ('019) and further in view of Clemens et al. (US 6,551,269). Dutcher et al., as modified above, describes the applicant's basic invention, with the exception of the shroud being collapsible. Attention is directed to the

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secondary reference of Clemens et al., that discloses a lead delivery device that has a protective body 16 with a lead lumen 20 which is made of a material at a specific thickness that allows the lumen to collapse, (Col. 3, lines 3-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the protective shroud of Dutcher et al. with the material and thickness disclosed by Clemens et al. in order to make it easier for removal from the implantation site (see abstract).

13. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Brucker et al. (US 5,500,012). Dutcher et al., as described above, discloses the applicant's basic invention with the exception of the carrier body having mapping electrodes and the distal end portion being configured for articulated movement using means at the proximal end. Attention is directed to the secondary reference of Brucker et al., which discloses a catheter for delivering an ablation electrode to the heart (Col. 3, lines 40-46). The catheter has electrodes 22a-22n at the distal tip which provide local activation mapping (Col. 3, lines 49-52), and the distal end is also configured for articulated movement by pulling on wire 25 at the proximal end (Col. 4, lines 7-10 and 44-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to add mapping electrodes and articulated movement in order to locate the best treatment site and then maneuver the tip into the best position to deliver treatment (Col. 2, lines 20-25 and Col. 3, lines 62-63).

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14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Kristiansen ('431) and further in view of Ricciardelli et al. ('957).

Dutcher et al., as modified above, discloses the applicant's basic invention with the exception of a journaled handle assembly for effectuating axial rotation of the carrier body. Attention is directed to the secondary reference of Ricciardelli et al., that discloses a journaled handle assembly comprising handle 15, shaft 16, and carrier body 10, such that by gripping the handle, the carrier body could then be axially rotated around the shaft by turning the body (see figure 1 and Col. 6, lines 22-26). Therefore, it would have been obvious to one of ordinary skill in the art to modify the delivery system of Dutcher et al. by adding the journaled handle assembly of Ricciardelli et al. since this is an old and well known method in the art for rotating carrier bodies to assist in delivering leads to implantation sites.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Kristiansen ('431) and further in view of Dutcher et al. ('019).

Dutcher et al. ('847), as modified above, disclose the applicant's basic invention with the exception of having the distal end of the carrier body tapered to form a shroud.

Attention is directed to the secondary reference of Dutcher et al. ('019), which shows in figure 1 the distal end of carrier body 10 having tapered part 16 which helps form a shroud around the helix 42. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the delivery system of Dutcher et al. ('847) by adding a tapered distal end in order to add a shroud that protects the helix prior to implantation.



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16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Kristiansen ('431) and Dutcher et al. ('019) and further in view of Clemens et al. (US 6,551,269). Dutcher et al., as modified above, describes the applicant's basic invention, with the exception of the shroud being collapsible. Attention is directed to the secondary reference of Clemens et al., that discloses a lead delivery device that has a protective body 16 with a lead lumen 20 which is made of a material at a specific thickness that allows the lumen to collapse, (Col. 3, lines 3-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the protective shroud of Dutcher et al. with the material and thickness disclosed by Clemens et al. in order to make it easier for removal from the implantation site (see abstract).

17. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher et al. ('847) in view of Kristiansen ('431) and further in view of Brucker et al. (US 5,500,012). Dutcher et al., as modified above, discloses the applicant's basic invention with the exception of the carrier body having mapping electrodes and the distal end portion being configured for articulated movement using means at the proximal end. Attention is directed to the secondary reference of Brucker et al., which discloses a catheter for delivering an ablation electrode to the heart (Col. 3, lines 40-46). The catheter has electrodes 22a-22n at the distal tip that provide local activation mapping (Col. 3, lines 49-52), and the distal end is also configured for articulated movement by pulling on wire 25 at the proximal end (Col. 4, lines 7-10 and 44-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

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applicant's invention to add mapping electrodes and articulated movement in order to locate the best treatment site and then maneuver the tip into the best position to deliver treatment (Col. 2, lines 20-25 and Col. 3, lines 62-63).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
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Eric D. Bertram  
Examiner  
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EDB